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EXAMINER
GRIARES, T

12M2/0518

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ART UNIT PAPER NUMBER
1205 6

DATE MAILED: 05/18/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on Mar. 14, 1994 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire Three(3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 11-26 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-10 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 11-26 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved, ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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EXAMINER'S ACTION

Serial Number: 08/071,052
Art Unit: 1205

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I. The papers filed March 14, 1994 have received and entered.

II. Claims 11-26 are the active claims in the application.

Claims 1-10 have been canceled.

III. The claims are drawn to a method of treating atherosclerosis with a combination of aspirin and vitamins.

IV. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

V. The specification is again objected to under 35 U.S.C. § 112, first paragraph, as the proportions of active agents present in the synergistic compositions are not clearly set forth in the specification. The dose ranges on page 13 do not set forth what ratios of active agents will yield the desired synergistic effect. The applicant argues that the amounts would be obvious to the skilled artisan. However, applicant is claiming a synergistic effect which is not clearly demonstrated on the record. The active agents individually are admitted to possess the characteristics claimed. There is no clear teaching of the proportions needed to effect the synergistic activity.

Claims 11-26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 11-26 fail to recite the active agents or the ratio of active agents which will yield the synergistic effect. The declaration indicates that a combination of Vitamins and minerals are used and not a single vitamin or mineral as claimed in 13-23.

The claims are not commensurate with the scope of the data which applicant argues shows a synergistic activity. The data does not teach that each of the medicaments claimed in claims 11-26 are effective ~~by~~ individually or in a prescribed combination. VII. Claims 11-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Igarashi et al (778), Fratzer (603) and Frisbee (081). Igarashi and Fratzer each teach in their abstracts the use of Vitamin E to treat a vascular disease and Frisbee discloses at column 1, lines 25 to 30 that aspirin can be used to treat vascular diseases.

It is deemed well settled patent law that the combination of ingredients of known character where the results obtained are no more than additive of the individual character will not be patentable. It is clear from applicants admissions that each of the claim designated ingredients are known to have beneficial results in patients. The use of the two ingredients or three in a single combination would have been obvious to those skilled in the art given the known characteristics of each component.

The declaration of Dr. Larry H. Hollier has been carefully reviewed but is ~~not~~ deemed persuasive. The copy of the graphs provided the examiner do not show a distinction between the bars.

As there is no clear explanation as to their relationship it appears that the bars show an additive effect rather than a synergistic effect.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In *re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In *re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960). As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art.

In this application it would have been prima facie obvious to administer aspirin and a multiple vitamin conjointly to treat heart conditions. The effects claimed in claims 11-16 on the prostaglandin function in platelets and migration of cholesterol would be inherent in the individual administration of the claimed active agents.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

VIII. None of the claims are allowed.

IX. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P.

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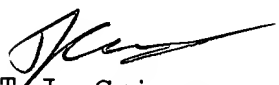
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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

X. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Criares whose telephone number is (703) 308-4607.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


T.J. Criares
May 17, 1994


MARIANNE M. CINTINS
SUPERVISORY PATENT EXAMINER
GROUP 120